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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,705

10/03/2006

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EXAMINER

RANADE, DIVA

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,705	<b>Applicant(s)</b> KAAL ET AL.	
	<b>Examiner</b> DIVA RANADE	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/25/09</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent 5,114,404 to Paxton et al.

a. Claim 1: Paxton shows a plunger for a retractable syringe (20) having a spring (51 and/or 72) and a needle mount (58), said plunger comprising a first plunger member (20) and a second plunger member (76) that are capable of being releasably and rotationally engageable (See Column 7 lines 43-67 and Column 8 lines 1-4) to co-operatively maintain said spring in an initial compressed state, arranged so that rotational disengagement (See Column 7 lines 43-67 and Column 8 lines 1-4) of said first plunger member and said second plunger member can facilitate decompression of said spring from the initial compressed state when required to force retraction of said first plunger member and said needle mount when engaged therewith (Column 7 lines 65-67), following depression of said plunger to deliver fluid contents of said syringe.

b. Claim 2, 8: Paxton shows that the first plunger member and the second plunger member are capable of being releasably engageable by a bayonet coupling ((See Column 7 lines 43-67 and Column 8 lines 1-4).

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c. Claim 3, 9: Paxon shows wherein the plunger member is engageable with the needle mount (via connection with (54) to needle mount (58)) to facilitate rotation of the first plunger member relative to the second plunger member (76) (See Column 7 lines 60-67).

a. Claim 4, 10: Paxon shows that the first plunger member comprises a needle mount engagement device (54 release mechanism bottom portion attaches to needle mount also See Column 4 wherein lines 56-65 describe how the plunger rod is directly coupled with the needle release or needle mount engagement device, therefore the plunger comprises a needle mount engagement device).

b. Claim 6, 13: Paxon shows wherein the second plunger member comprises a seal (105) (See Fig 6 and 7)) mounted thereto.

c. Claim 7: Paxon shows a retractable syringe comprising a plunger (20), a barrel (12), a spring (51) and a needle mount (58), said plunger comprising a first plunger member (20) and a second plunger member (76) that are capable of being releasably and rotationally engaged (See Column 7 lines 43-67 and Column 8 lines 1-4) to co-operatively maintain said spring in an initial compressed state and are rotationally disengageable (See Column 7 lines 43-67 and Column 8 lines 1-4) to facilitate decompression of said spring to force retraction ( See Fig 6 and 7) of said first plunger member and said needle mount, when engaged therewith, following depression of said plunger to deliver fluid contents of said syringe.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,114,404 to Paxton et al in view of U.S. Patent 5,211,628 to Marshall and further in view of U.S. Publication 2003/0158525 to Thorley et al.

d. Claim 5, 11: Paxton teaches a tooth and groove arrangement of the needle mount engagement (62 See Column 5 lines 35-40) but lacks barbed arms.

Marshall shows that the needle mount engagement device comprises two barbed arms (56). It would have been obvious to one of ordinary skill in the art during the time of the invention to substitute one of these obvious variants for the other to accomplish the same task.

e. Claim 12: Paxton teaches a tooth and groove arrangement of the needle mount engagement (62 See Column 5 lines 35-40) and shows a needle mount recess to engage the mount engagement but lack recesses that are respectively engaged by the barbed arms. Marshall shows needle mount comprises recesses (see recesses inside lips 36 in Fig 4) that are respectively engageable by the barbed arms. It would have been obvious to one of ordinary skill in the art during the time of the invention to substitute one of these obvious variants for the other to accomplish the same task.

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2. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 5,114,404 to Paxton et al in view of U.S. Patent 5,211,628 to Marshall.

f. Claims 14 and 15: Paxon lacks a collar mounted to the barrel. Instead Paxon employs a ratchet sleeve which prevents the plunger from further use. Thorley shows a collar mounted onto the barrel. The collar of Thorley comprises one or more projections capable of co-operating with one or more abutments of said first plunger member to form a plunger disabling means device that is capable of preventing subsequent depression and/or withdrawal of said first plunger member following retraction of the needle mount as in claim 15 (See [0016]). It would be obvious to one skilled in the art during the time of the invention to add the collar of Thorley to the barrel of Paxon on the ribs of the plunger in order to provide a locking means or ensure disablement of the plunger of Paxon.

g. Claim 16: Paxon lacks a collar mounted to the barrel. Instead Paxon employs a ratchet sleeve which prevents the plunger from further use. Thorley shows a collar mounted onto the barrel wherein the one or more projections comprise a pawl (422A) but lack two pawls that are engageable with a respective step (475) on said first plunger member to co-operably prevent subsequent depression said first plunger member following retraction of the needle mount and thereby prevent syringe re-use. It would be obvious to one skilled in the art during the time of the invention to add more pawls to increase efficacy of locking mechanism.

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h. Claim 17: Paxon lacks a collar mounted to the barrel. Instead Paxon employs a ratchet sleeve which prevents the plunger from further use. Thorley shows a collar mounted onto the barrel wherein the one or more projections comprise a rib (422B) but lacks two ribs that are engageable with a respective ledge (474) on said first plunger member to co-operably prevent subsequent withdrawal of said first plunger member following retraction of the needle mount and thereby prevent syringe re-use. It would be obvious to one skilled in the art during the time of the invention to add more ribs to increase efficacy of locking mechanism or to guide plunger through the barrel.

i. Claim 18: Paxon shows a retractable syringe comprising:

[[i]] a barrel (12);

[[ii]] but lacks a collar mounted to the barrel and comprising two ribs and two pawls; (Modify Marshall with Thorley, See above)

[[iii]] a retraction spring (51);

[[iv]] a needle mount (58) located at a needle end of the barrel (See Fig 6); and

[[v]] a plunger (20) operably located in said barrel and engageable with said needle mount, said plunger comprising:

[[a]] a first plunger member (20) (modified by Thorley See claim 16 and 17 rejection) having two steps and two ledges; and

[[b]] a second plunger member (76) and a seal (105) mounted thereto;

wherein the first plunger member and the second plunger member are releasably coupled to co-operatively maintain said spring in an initial compressed

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state and can subsequently be rotatably uncoupled to facilitate decompression of said spring to force retraction of said first plunger member and said needle mount when engaged therewith following depression of said plunger to deliver fluid contents of said syringe ((See Column 7 lines 43-67 and Column 8 lines 1-4)) and wherein said two pawls are engageable with respective steps on said first plunger member to co-operably prevent subsequent depression said first plunger member and said two ribs are engageable with respective ledges on said first plunger member to co-operably prevent subsequent withdrawal of said first plunger member following retraction of the needle mount and needle (See rejection for claims 16 and 17 above).

j. Claim 19: Paxton shows that the syringe is arranged so that following retraction of the first plunger member (20), the needle mount (58) and needle (70), said second plunger member (76) and said seal (105) remain at a needle end the barrel thereby preventing refilling and re-use of the syringe (See Fig 6 and 7).

12. Claims 20-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent 5,114,404 to Paxton et al.



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n. Based on the disclosure of Paxton it would be obvious to one skilled in the art to use the method described in claim 20-35 in order to assemble the syringe in a functional manner.

### ***Response to Amendment***

1. The amendment filed 08/25/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the disclosure Page 4 lines 15-19, Page 9 lines 8-10, and page 10 lines 1-20 disclose that the first and second plunger members may be rotationally uncoupled or disengaged and states no where in the disclosure that the two are rotationally engaged. In fact there are known couplings which may snap engage and then rotationally disengage without ever being able to rotationally engage. In sum, rotational engagement of the two plungers is not supported by the specifications.

Applicant is required to cancel the new matter in the reply to this Office Action. In efforts of compact prosecution the examiner has still acknowledged the claim language in the rejection.

### ***Response to Arguments***

Although Paxton has been used as a primary reference in this action, the Examiner still finds Marshall to be reasonable prior art.

***Conclusion***

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DIVA RANADE/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763